General

Guideline Title

Surgical management of pancreatic necrosis: a practice management guideline from the Eastern Association for the Surgery of Trauma.

Bibliographic Source(s)

Mowery NT, Bruns BR, MacNew HG, Agarwal S, Enniss TM, Khan M, Guo WA, Cannon JW, Lissauer ME, Duane TM, Hildreth AN, Pappas PA, Gries LM, Kaiser M, Robinson BRH. Surgical management of pancreatic necrosis: A practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2017 Aug;83(2):316-27. [50 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
UNKNOWN	Multidisciplinary Group

UNKNOWN	Methodologist Involvement
▮▯▯▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▯▯▯	External Review
▮▯▯▯▯	Updating

Recommendations

Major Recommendations

The strength of recommendation (strong or weak/conditional) and levels of evidence (high, moderate, low or very low) are defined at the end of the "Major Recommendations" field.

Results Obtained for Operative Timing in Pancreatic Necrosis (Population, Intervention, Comparator, and Outcome [PICO] 1)

In adult patients with pancreatic necrosis (P) does early surgery (I) compared with late surgery (C) decrease mortality rates (O)?

Recommendation

The panel determined that the quality of evidence was low overall; the panel also considered that most patients would place a high value on the potential 50% reduction in mortality seen with delaying surgery. Although the exact number of how long to delay is in question, it would appear that delaying at least 12 days and potentially 30 days would lead to additional decreases in mortality. This allows for a strong recommendation due to patient preference. Thus, in adult patients with pancreatic necrosis, the panel recommends that pancreatic necrosectomy should be delayed until at least day 12, as opposed to earlier necrosectomy.

Results Obtained for Adjuvant Therapy Use in Pancreatic Necrosis (PICO 2)

In adult patients with pancreatic necrosis (P), does primary surgical intervention (I) compared with percutaneous drainage (PCD) (C) or endoscopic drainage (DEN) (C) decrease mortality rates (O)?

Recommendation

The overall quality of evidence for the topic is very low. PCD and endoscopic debridement may have a role in the management of pancreatic necrosis at times as a definitive treatment. It certainly has value as a means to delay surgical intervention until a time that it is safe. Pursing PCD or DEN as primary therapy has a questionable effect on mortality but has been shown to increase the number of total procedures. This would have a corresponding effect on hospital days and potentially health care costs. Numerous studies, including the panels' analysis, show equivalence in the different types of interventions suggesting health care teams have the ability to tailor care to the individual patient. This allows for a conditional recommendation based on the ability to choose which options fit the patient best.

Recommendation: In adult patients within the first 30 days of symptoms with infected necrotic collections, the panel conditionally recommends surgical debridement only if the patient fails to improve after radiologic or DEN. After 30 days, all 3 means of drainage have equivalent results.

Results Obtained for Surgical Approach to Pancreatic Necrosis (PICO 3)

In adult patients undergoing surgery for pancreatic necrosis (P) do minimally invasive approaches (I) compared with open approaches (C) decrease the mortality rate (O)?

Recommendation

The overall quality of evidence was rated as low. The panel considered that most patients would place a high value on the potential three-fold reduction in postoperative organ failure and 50% reduction in mortality. This allows for a strong recommendation.

In adult patients with pancreatic necrosis, even documented infected necrosis, the panel recommends that patients undergo a step-up approach to surgical intervention. This includes aggressive use of percutaneous drains as a means to delay or even definitively treat necrosis which may be the real benefit of this surgical pathway rather than the actual surgical incision. This recommendation is based on low-quality evidence and is associated with significant patient benefit.

Definitions

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
High	Very confident that the true effect lies close to estimate of effect
Moderate	Moderate effect; true effect is likely close to estimate of effect but may be substantially different
Low	Limited confidence; true effect may be substantially different from estimate of effect
Very Low	Little confidence; true effect likely substantially different from estimate of effect

GRADE Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

makers	Strong Recommendation	Weak/Conditional Recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pancreatic necrosis

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Critical Care

Endocrinology

Gastroenterology

Internal Medicine

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide evidence-based recommendations to be used to direct the decision-making processes related to the surgical management of patients with pancreatic necrosis

Target Population

Adult patients admitted with pancreatic necrosis

Interventions and Practices Considered

1. Immediate necrosectomy versus delayed necrostomy
2. Primary surgical necrosectomy (open or retroperitoneal) versus primary endoscopic transgastric necrosectomy or primary percutaneous drainage (PCD)
3. Transperitoneal approach (open necrosectomy) versus minimally invasive/step-up approach

Major Outcomes Considered

- Mortality
- Length of stay
- Intensive care unit length of stay
- Cost
- Ventilator-free days

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Inclusion Criteria for This Review

Study Types

In constructing the Grading of Recommendations Assessment, Development and Evaluations (GRADE) recommendations, only studies with comparison groups were included. This included randomized controlled trials, prospective observational or retrospective studies, and case control studies. Additional support was based on case studies to give a complete picture of the current literature. Meta-analyses, letters, and reviews containing no original data or comments were excluded.

Participant Types

The panel included studies of adult patients without restricting sex, ethnicity, or degree of comorbidity. Only studies pertaining to the treatment of hospitalized patients with necrotizing pancreatitis were included.

In the more recent literature, the distinction between infected and sterile necrosis has been obscured. Since the included studies focused on surgical intervention for pancreatic necrosis, and the traditional treatment of infected necrosis was surgery, many of the included patients carried the diagnosis of infected necrosis. How the diagnosis of infected necrosis was reached varied greatly, and all included studies have patients that were labeled as infected. More recent studies do not make the distinction between infected and sterile necrosis as they move through the algorithm but rather discuss delaying intervention for both until maturation of the process. Given this evolution in treatment, the panel did not exclude or limit the included patients or studies based on the presence of infection.

Intervention Type

The first population, intervention, comparators, and outcome (PICO) question examined the operative timing. The definition of early and late surgical intervention has evolved over time and varies from study to study. Although prospective randomized data do exist on the subject, trying to find multiple studies required the inclusion of subsets of larger studies. Three separate analyses were performed to examine

the potential clinically relevant timeframes. Analysis of greater and less than 72 hours was used to look at a period that defined very early intervention that was common in the early 1980s and is still used by some surgeons in infected necrosis. An intermediate value of 12 days for the cutoff of early/late was included to address the numerous studies that have used the 10-day to 14-day mark as a timeframe for surgical intervention. Finally, a 30-day definition of early and late was used due to the recent literature.

The second PICO question compares surgical intervention to the two main alternatives, percutaneous and endoscopic drainage (DEN). There is limited data directly comparing surgery to each of the alternative methods of drainage but some indirect comparisons can be made. In the case of percutaneous methods, many of the minimally invasive surgical techniques include percutaneous drainage (PCD) as a preoperative intervention. A certain percentage of the patients have resolution of their disease with percutaneous intervention alone giving an opportunity for additional comparison groups. The other complicating factor is that surgery is used as a salvage procedure for both failed percutaneous intervention and DEN. This selects the surgical population for poor outcomes.

Finally, the third PICO question addressing open versus minimally invasive intervention has small numbers but with the most uniform outcomes.

Outcome Measure Types

Outcomes were chosen by the committee and the uniformity of their presence in the literature was examined. Outcomes were rated in importance from 1 to 9, with scores of 7 to 9 representing critical outcomes. The following outcomes were considered by the committee: length of stay, intensive care unit length of stay, cost and ventilator-free days. However, all of these criteria were deemed noncritical for the decision-making process within the GRADE framework. Also, the available literature did not provide sufficient or consistent measurements across the studies, specifically if the onset of related conditions, such as renal or respiratory failure, occurred before or after surgical intervention. Mortality was deemed a critical outcome for the decision-making process across all PICO questions, and this was chosen as the primary outcome measure.

Review Methods

Search Strategy

A computerized search of the National Library of Medicine MEDLINE database was undertaken using the PubMed Entrez interface. English language citations during the period of January 1980 through December 2014 using the primary search strategy: Pancreatic necrosectomy[mh] AND humans[mh] AND English NOT (reviews[pt] OR letter[pt] OR comment[pt] OR news[pt]).

The PubMed-related articles algorithm was also used to identify additional articles similar to the items retrieved by the primary strategy. Of the 283 articles identified by these two techniques, those dealing with either prospective or retrospective studies examining the management of pancreatic necrosis were selected, comprising 88 institutional studies evaluating diagnosis and management of adult patients with pancreatic necrosis (see Figure 1 in the original guideline document). For a complete listing of the articles reviewed and considered for inclusion please see the table in the supplemental digital content (see the "Availability of Companion Documents" field). The articles were reviewed by a group of nine surgeons who collaborated to produce this practice management guideline (PMG). When discrepancy existed about inclusion or data extracted, the majority among the three reviewers to read each article was used.

Number of Source Documents

Number of studies included in quantitative synthesis (meta-analysis):

Population, intervention, comparators, and outcome (PICO) #1: 8
PICO #2: 10
PICO #3: 5

Refer to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure 1) in the original guideline document.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Methodology Levels for Rating the Quality of Evidence

Quality Level	Definitions
High	Very confident that the true effect lies close to estimate of effect.
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Very Low	Little confidence; true effect likely substantially different from estimate of effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Meta-analysis was performed using REVMAN 5 online data analysis (The Cochrane Collaboration, Informatics & Knowledge Management Department, London, United Kingdom) to give an overall point estimate and confidence interval for the effect size that the intervention had on the outcome of interest. Evidence tables were created by collating the committee members reviews and GradePRO online software .

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline has been developed using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) framework that was adopted by Eastern Association for the Surgery of Trauma in 2012.

This practice management guideline (PMG) addresses three population, intervention, comparators, and outcome (PICO) questions that would be answered by the available evidence to guide surgical treatment decisions in caring for patients with pancreatitis-associated necrosis (see Table 1 in the original guideline document).

The recommendations flowed from the outcomes of the meta-analysis and wording was reached by critical evaluation of several drafts of the recommendations. In points of disagreement the majority vote ruled.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Definition of Strong and Weak Recommendation

	Strong Recommendation	Weak/Conditional Recommendation
For patients	Most patients would want the recommended course of action.	Most patients would want the recommended course of action, but many would not.
For clinicians	Most patients should receive the recommended course of action.	Different choices will exist for different patients, and clinicians should help patients decide.
For policy makers	Recommended course should be adopted as policy.	Considerable debate and stakeholder involvement needed to make policy.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Several case series underscore that mortality decreases when interventions are postponed. As advocated in guidelines by the International Association of Pancreatology in 2002, delay in open surgery for at least 3 weeks to 4 weeks leads to lower morbidity and mortality rates. With delay in intervention, demarcation of necrotic from vital tissue occurs, so that if necrosectomy is performed, resection of vital tissue is minimized. This leads to better long-term endocrine and exocrine function and a reduction in postoperative adverse events.
- The use of less invasive techniques allows surgical debridement to be deferred or avoided altogether.
- It has been shown that placement of percutaneous catheter drains can delay surgery and allow for decreased mortality.

- Combining a percutaneous approach with endoscopic transmural drainage can prevent external fistulae and avoid repetitive endoscopic interventions to perform direct necrosectomy. Irrigation through the percutaneous approach with egress through the transmural fistula results in a form of debridement. In case-control series from a single center, the combined percutaneous-endoscopic approach has been shown to increase the rate of nonsurgical resolution and result in a decrease in hospitalization, time to drain removal, number of computerized tomography (CT) scans, and number of drains compared to percutaneous catheter drainage (PCD) alone.
- Advantages of nonsurgical approaches include a reduction in systemic complications after intervention and a lower risk of developing new organ failure.
- Minimally invasive approaches are thought to induce less stress than open surgery in already critically ill patients.

Potential Harms

- Adverse events, such as external fistulae, occur in up to 27% of patients with percutaneous catheter drainage (PCD) as the primary treatment for pancreatic necrosis.
- A major limitation of PCD is the development, in at least 20% of patients, of pancreaticocutaneous fistulae, some of which do not close because of communication of the drain with an upstream disconnected pancreatic duct.
- Local adverse events including bleeding and fistula seem to be slightly increased in some retrospective studies when minimally invasive treatment regimens are used, although this finding may reflect a difference in the definition of adverse events or represent a learning curve associated with early results.

Qualifying Statements

Qualifying Statements

- The Eastern Association for the Surgery of Trauma (EAST) is a multi-disciplinary professional society committed to improving the care of injured patients. The Ad Hoc Committee for Practice Management Guideline Development of EAST develops and disseminates evidence-based information to increase the scientific knowledge needed to enhance patient and clinical decision-making, improve health care quality, and promote efficiency in the organization of public and private systems of health care delivery. Unless specifically stated otherwise, the opinions expressed and statements made in this publication reflect the authors' personal observations and do not imply endorsement by nor official policy of EAST.
- "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* These guidelines are not fixed protocols that must be followed, but are intended for health care professionals and providers to consider. While they identify and describe generally recommended courses of intervention, they are not presented as a substitute for the advice of a physician or other knowledgeable health care professional or provider. Individual patients may require different treatments from those specified in a given guideline. Guidelines are not entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. While guidelines can be written that take into account variations in clinical settings, resources, or common patient characteristics, they cannot address the unique needs of each patient nor the combination of resources available to a particular community or health care professional or provider. Deviations from clinical practice guidelines may be justified by individual circumstances. Thus, guidelines must be applied based on individual patient needs using professional judgment.
- The overriding principle of interventions for necrosis is that no single approach is optimal for all patients. The best approach is multimodal and adaptable to the individual patient to achieve the best outcomes.

*Institute of Medicine. Clinical practice guidelines: directions for a new program. MJ Field and KN Lohr (eds) Washington, DC: National Academy Press. 1990: pg 39.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mowery NT, Bruns BR, MacNew HG, Agarwal S, Enniss TM, Khan M, Guo WA, Cannon JW, Lissauer ME, Duane TM, Hildreth AN, Pappas PA, Gries LM, Kaiser M, Robinson BRH. Surgical management of pancreatic necrosis: A practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2017 Aug;83(2):316-27. [50 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Aug

Guideline Developer(s)

Eastern Association for the Surgery of Trauma - Professional Association

Source(s) of Funding

Eastern Association for the Surgery of Trauma (EAST)

Guideline Committee

Expert Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

The authors declare no conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of Trauma and Acute Care Surgery Web site .

Availability of Companion Documents

The following is available:

> Kerwin AJ, Haut ER, Burns JB, Como JJ, Haider A, Stassen N, Dahm P, Eastern Association for the Surgery of Trauma Practice Management Guidelines Ad Hoc Committee. The Eastern Association of the Surgery of Trauma approach to practice management guideline development using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. J Trauma Acute Care Surg. 2012 Nov;73(5 Suppl 4):S283-7. Available from the Eastern Association for the Surgery of Trauma (EAST) Web site .

Supplemental digital content is available from the Journal of Trauma and Acute Care Surgery Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on October 20, 2017. The information was verified by the guideline developer on November 22, 2017.

This NEATS assessment was completed by ECRI Institute on September 26, 2017. The information was verified by the guideline developer on November 22, 2017.

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